K120490

NIPRO MEDICAL CORPORATION

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DEC 27 2012

510(k) Summary – Quick Sampler Holder

807.92(a) (1)

Contact Person: Jessica Oswald
Regulatory Affairs Specialist

Date of summary preparation: January 19, 2012

807.92(a) (2)

Trade Name: Quick Sampler Holder
Common Name: Blood specimen collection device
Classification Name: tubes, vials, systems, serum separators, blood collection
Regulation Number: 862.1675
Regulatory Class: II
Panel: Clinical Chemistry
Product Code: JKA

807.92(a) (3)

Legally marketed substantial equivalent device: ITL Samplok Luer Kit (K021941)

807.92(a) (4)

Description of device:
The Quick Sampler Holder is a non-contacting patient device. It is intended to be used in conjunction with a vacuum blood collecting vessel and bloodlines with y-ports, for blood banking. The Quick Sampler Holder consists of a double ended 18 gauge needle attached to a blood tube holder. The proximal needle tip, which is inserted into the y-port, is blunt to prevent accidental needlesticks; the distal end, inside the holder, is sharp and is covered by a rubber sleeve to prevent blood loss during vial replacement/sample collection.

807.92(a) (5)

Indications for Use:
The Quick Sampler Holder is intended to be used as a part of vacuum blood collection equipment for the collection of blood samples for various types of blood tests

807.92(a) (6)

Comparison of technological characteristics:
The Quick Sampler Holder is identical to the predicate in terms of indications for use and mode of operation. It is substantially equivalent to the predicate in terms of functional, mechanical and material specifications. The only technological difference between the

two devices is the proximal tip. The quick Sampler holder has a blunt tip, whereas, the ITL Samplok has a luer tip.

807.92(b) (1)

Non-clinical tests submitted:

Performance characteristics: Integrity test of tamper sealing, Rubber sleeve functional tests, Hub –needle functional tests, Hub -Holder functional tests, Chemical and microbiological characteristics and Dimensional characteristics.

807.92(b) (2)

Clinical tests submitted:

No clinical testing required or submitted with this application.

807.92(b) (3)

Conclusions drawn from non-clinical and clinical tests:

Based on the testing described above, we believe the Quick Sampler Holder to be substantially equivalent to ITL Samplok, in terms of safety and effectiveness for its intended use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

December 27, 2012

Ms. Jessica Oswald-McLeod, ASQ CQA
Regulatory Affairs Specialist
Nipro Medical Corporation
3150 North West, 107th Avenue
MIAMI FL 33172

Re: K120490
Trade/Device Name: Quick Sampler Holder
Regulation Number: 21 CFR 862.1675
Regulation Name: Blood Specimen Collection Device
Regulatory Class: II
Product Code: JKA
Dated: September 11, 2012
Received: September 13, 2012

Dear Ms. Oswald-McLeod:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Kwame O. Ulmer

Anthony D. Watson, B.S., M.S., M.B.A
Director
Division of Anesthesiology, General Hospital,
Respiratory, Infection Control and
Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

K120490

Device Name: Quick Sampler Holder

Indications for Use:

The Quick Sampler Holder is intended to be used as a part of vacuum blood collection equipment for the collection of blood samples for various types of blood tests

Prescription Use ____X___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Sajjad H. Syed

Digitally signed by Sajjad H. Syed
DN: c=US, o=U.S. Government, ou=HHS, ou=FDA, ou=People, cn=Sajjad H. Syed, 0.9.2342.19200300.100.1.1=2000601742
Date: 2012.12.27 14:57:38 -05'00'

(Division Sign-Off)
Division of Anesthesiology, General Hospital Infection Control, Dental Devices

510(k) Number: K120490